

2724-504

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 12, 2014

Mr. James J. McFadden, Ph.D.
Senior Regulatory Project Manager
Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, IL 60173-5417

Subject: Acceptance of Combined Amending Labeling; Addition of *InfestStop™ & Direct Response to EPA Letter Dated September 30, 2011 RF2004 (CCSO), EPA Reg. No. 2724-504 Your Submissions Dated October 8, 2012 and March 28, 2013 & E-Resubmissions Dated March 5, 2013, May 28, 2013 and September 27, 2013

Dear Mr. McFadden

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with the following label revision provision(s):

Amendments to Cat Spot-On Product Registrations:

- 1. This registration is now time-limited, and will expire two (2) years from the date of this letter. More specifically, this registration will expire on February 12, 2016.**
2. If the Agency determines that future mitigation measures are necessary for all pet spot-on products, EPA will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.
3. Please consider limiting the formulations of this product to one basic confidential statement of formula. The Agency may require this in the future. In addition, it is possible that no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
4. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning April 1, 2014. Please flag any Confidential Business Information (CBI) as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division (Attn: Kaitlin Keller). The following is a list of information that must be included in the quarterly reports for each incident:
 - EPA Registration Number
 - Product name (brand name)
 - Lot #
 - Where purchased: Internet, store, veterinarian.
 - Active-ingredient(s)
 - Weight range for product
 - Date on which incident occurred. (mm/dd/yyyy)
 - State in which the incident occurred. (Standard 2 letter abbreviation)
 - Registrant case #
 - Species: Dog, cat, other (specify).
 - Breed: (As reported by pet owner)
 - Age: Months or years.
 - Sex: M, F, or neutered.
 - Weight: Pounds.

Conditions of Acceptance/Amendments to Cat Spot-On Product Registrations, continued:

- Primary Route of Exposure: Dermal, oral, other animal, inhalation, other.
 - Body System: Neurological, dermatological, GI, respiratory, ocular, other.
 - Major signs noted with separate column for each sign, using standard terminology.
 - Time to Onset: (Hours, days)
 - Treated by veterinarian: Yes or No
 - First time product used: Yes or No
 - Misuse: Use on incorrect species, overdose, too frequent dosing, other (describe).
 - Any known pre-condition.
 - EPA Severity Code: Death, major, moderate, minor.
 - Outcome: Died, recovered, still treated, unknown.
5. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
- All incidents should be reported, including all minor dermal and ocular irritation reports.
 - Summary table for cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - Summary table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
 - A summary table for cats showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
 - A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label.
 - A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range.
 - Table showing number of incidents for each cat breed.
 - Table showing number of incidents in cats for each clinical sign.
 - Table showing number of incidents in cats for each organ system.
 - Report aggregate incidents, but do not combine moderate and minor incidents.

Should you wish to add/retain a reference to the company's website, smart phone/tablet app and/or a QR code reader on your product label, please be aware that the website, smart phone/tablet app and/or a QR code reader becomes labeling under FIFRA and is subject to review by the Agency. If the website, smart phone/tablet app, and/or a QR code reader is false or misleading, the product would be misbranded and unlawful to sell or distribute under section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website, smart phone/tablet app, and/or a QR code reader is referenced on a product's label, claims made on the website, smart phone/tablet app, and/or a QR code reader may not be substantially differ from those claims approved through the registration process. Therefore, should the Agency find, or if it is brought to our attention that a website, smart phone/tablet app, and/or a QR code reader contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website, smart phone/tablet app, and/or a QR code reader will be referred to EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

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Copies of your label stamped "Accepted" as well as a review for minimum cat/kitten treatment weight are enclosed for your records. If you have any questions about this label review, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely Yours,



Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

Enclosures: *Label Stamped "Accepted," dated February 12, 2014* :
 Review for Minimum Cat/Kitten Treatment Weight, dated May 17, 2013 :
002724-00504 D471374 & D471380 :

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[] Optional Copy

RF2004 (CCSO)

Alternate brand names:

ZODIAC® Spot On® Plus Flea & Tick Control for Cats 5 lbs. and Over
ZODIAC® Spot On® Plus Flea & Tick Control for Cats & Kittens Under 5 lbs.
ZODIAC® Multi-Cat Spot On® Plus Flea & Tick Control for Cats 5 lbs. and Over

Include "Cat" in product brand name and font size must be 75% of the size of the largest letter in the brand name

[For] use ONLY on cats/kittens [over 3 lbs but less than 5 lbs.][and weighing][5 lbs. and over] & 12 weeks of age and older

ONLY For use on cats/kittens weighing [5 lbs and over][> 3 lbs but < 5 lbs][over 3 lbs but less than 5 lbs] & 12 weeks of age and older

(General/Protection claims)

1 ml [cc] [0.034 fl oz] for cats/kittens (12 weeks of age and older) over 3 lbs but less than 5 lbs.; 1.8 ml [cc] [0.061 fl oz] for cats 5 lbs. and over

Do not use more than one tube per cat

Flea & Deer Tick [Protective] for cats [& kittens (12 weeks of age and older)]

[Flea & deer tick] treatment for cats [& kittens (12 weeks of age and older)]

[Special formula for cats/kittens (12 weeks of age and older)][Superior flea prevention and treatment specially formulated for use on cats and kittens (12 weeks of age and older)]

Spot On [Topical][Non-systemic] treatment for [cats/kittens (12 weeks of age and older)]

Spreads [over time] with cat's movement (skin and hair oils)

Flea, Deer Tick, and Mosquito Treatment [Control][Prevention][Relief] for Cats & Kittens (12 weeks of age and older)

4 in 1 Control [Protection][Treatment] (Fleas, Flea Eggs, Deer Ticks, and Mosquitoes)

5 in 1 Control [Protection][Treatment] (Fleas, Flea Eggs, Flea Larvae, Deer Ticks, and Mosquitoes)

[1 month][monthly][flea, deer tick, & flea egg] protection

Monthly treatment for [fleas, flea eggs, & deer ticks]

Flea [and deer tick][and mosquito] control for your cat/kitten (12 weeks of age and older)

A smart approach to flea control

[Brand] Provides a novel [smart] approach to flea, deer tick, and mosquito control

Improved flea, deer tick, and mosquito control

Keeps fleas, deer ticks, and mosquitoes under control

[Advanced] Spot On [Plus] Insect Control [Treatment and Prevention]

A flea control program

Controls flea, deer tick, and mosquito problems [on your cat/kitten (12 weeks of age and older)]

Pet assured flea, deer tick, and mosquito protection

Provide your cat with flea, deer tick, and mosquito protection, right from the start

Direct on-animal protection from fleas, deer ticks, and mosquitoes

Provides relief [protection] from fleas, deer ticks, and mosquitoes

Once-a-month [topical][Spot On] protection from fleas, and deer ticks,

Reapply monthly][Suitable for year-round use][Month][sticker for home calendar

Monthly application for most effective protection

When it comes to fleas and deer ticks, there's no room for compromise [Brand Name]

[Satisfaction guaranteed or your money back] [money back guarantee]

(Kills/Repels/Controls claims)

[Actively] Kills [Controls] [adult] fleas, deer ticks, [larvae], and flea eggs for [up to][4 weeks][1 month][per application]

[Actively] Kills [fleas][deer ticks][flea eggs][larvae][&][and][mosquitoes][by contact]Kills [and/or Repels] mosquitoes [for up to 28 days][by contact]

[Protects for up to [Four/4] Weeks][One month][Flea][Deer Tick][Mosquito] Treatment]

[1 month][monthly][flea, deer tick, & flea egg][protection]

ACCEPTED
February 12, 2014
Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

EPA. Reg. No. 2724-504

Controls fleas, deer ticks, and mosquitoes & prevents flea reinfestations
 [Kills deer ticks] (for up to 1 month [4 weeks]) [per application]
 Starts killing fleas in 15 minutes
 Starts working [on/by] contact
 [Kills adult fleas, deer ticks, mosquitoes, flea eggs and flea larvae][Dual protection (against fleas and deer ticks)]
 [Dual action kills adult fleas and prevents flea development] ;
 Protects your [cat][kitten (12 weeks of age and older)] from fleas, deer ticks, and mosquitoes (which may transmit heartworm) ;
 Effectively controls fleas, deer ticks, and mosquitoes ;
 Kills [Controls] deer ticks that may transmit [][Lyme disease][and Cytauzoonosis] for up to [1 month][4 weeks]
 Protect your [cat] from [against] deer ticks that may transmit Lyme disease ;
 Kills [and repels] mosquitoes that may transmit heartworm ;
 Prevents mosquitoes from feeding on cats ;
 Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation
 Preventative treatment for fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation
 Controls fleas, deer ticks, and mosquitoes that cause highly irritating [insect] bites

(More general claims)

[All text below represents one label statement with any selected line]
 [Protect your family and cat from:]
 [When your cat has fleas and ticks, your family and cat/kitten may be exposed to:]
 Fleas that may cause:
 [Flea allergy dermatitis]
 [Flea bite anemia]
 [Tapeworm infestation]
 Deer ticks which may carry: Lyme disease
 [Zodiac] protecting pets for over 35 years

(Flea egg/life cycle claims)

[Plus][Contains][With] PRECOR® [vIGRen®][S-Methoprene][*InfestStop™], the first insect growth regulator for flea control
 Contains [Features][*InfestStop™] an Insect Growth Regulator (IGR) to inhibit the development of flea eggs
 Flea control for cats with [PRECOR®][vIGRen®] [*InfestStop™] Insect Growth Regulator (IGR) [(S)-Methoprene][*InfestStop™] Insect Growth Regulator (IGR) interrupts the development of the flea life cycle [at the egg stage]
 [(S)-Methoprene][*InfestStop™] Insect Growth Regulator (IGR) prevents the development of flea eggs into adult fleas and [inhibits the development of flea eggs into adult fleas]
 Controlling flea reproduction is the first step in controlling flea populations on your cat/kitten
 [(S)-Methoprene][*InfestStop™] Insect Growth Regulator (IGR) prevents flea reinfestation on your cat/kitten
 Flea treatment and preventative with an [insecticide] adulticide and [*InfestStop™] Insect Growth Regulator (IGR)
 [With [S-Methoprene][*InfestStop™] Insect Growth Regulator [IGR] to Break Flea Life Cycle]
 [Contains [*InfestStop™] an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for [1 month][30 days][4 weeks]

Kills [Controls] flea eggs for up to [30 days][1 month][4 weeks][per application]
 Kills flea eggs, the source of home flea infestations and pet re-infestations, for up to [30 days][1 month][4 weeks]
 [Kills][Prevents][Keeps] flea eggs from hatching for up to [30 days][1 month][4 weeks]
 Prevents flea eggs from developing into biting adults for up to [30 days][1 month][4 weeks][per application]

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An effective flea topical [A Spot On] product that kills adult fleas and halts the development of flea eggs [immature stages in the flea life cycle]
 Kills [flea] eggs before they hatch into biting adults
 Prevents re-infestation for up to [1 month][30 days][4 weeks]
 Kills hatching [developing] flea eggs
 Interrupts normal flea development [Stops the flea life cycle]
 Interrupts the flea life cycle
 Breaks the flea life cycle for up to [1 month][4 weeks][30 days]
 Controls[Kills][Lasts][Works][Protects] flea infestations for up to [1 month][4 weeks][30 days]
 One-two punch controls fleas and flea eggs
 Controls existing fleas and flea eggs, plus [and][prevents] future flea infestations
 Plus kills flea eggs and larvae to prevent future infestations
 *S-Methoprene (Must occur on same panel wherever InfestStop™ is used)

(Application claims)

[#] pack [# days] [#] doses [1/2/3/4/5/6] months supply
 One tube gives [1 month][4 weeks] of protection
 [Pre-measured][Convenient][and][&][No mess][easy][simple] to [use][handle][apply] disposable applicator [tube]
 Convenient [and effective], once-a-month [liquid][topical][Spot On] solution
 Practical solution
 Simple choice [flea & deer tick control]
 A [One] simple application provides your cat with protection for up to [1 month]
 Apply to one spot for head to tail (total body) flea protection [control]
 Apply to 1 spot - spreads over the cat's [entire] body [from head to tail] through [ordinary][innate][native] skin oils
 Spreads [over time] with cat's [ordinary][innate][native] skin oils
 [Plus] Contains a [biologically sourced] coat conditioner

[Once][One] Monthly Application

Easy to use [once] monthly application [liquid] prevents [and controls] fleas [& deer ticks]
 Reapply [Repeat] [once] monthly
 Repeat [treatment] every month
 Monthly Control [Relief][treatment]

(Applicator claims)

Unique Applicator [tube] Shape [Design][helps prevents misuse on dogs][helps prevents misapplication on dogs]
 Unique shape [for cats & kittens (12 weeks of age and older) 5 lbs and over] for cats & kittens (12 weeks of age and older) over 3 lbs but less than 5 lbs]
 Pet Specifix® Applicator Accu-Tip Dispenser
 [X] Pro-cision Flo™ Applicators [tubes]
 [Exclusive][Pinpoint][Applicator] for [pinpoint][exact][direct][easy][direct to skin] application
 Patent pending
 For pinpoint accuracy
 Direct to your cat's skin
 Easily penetrates hair
 The [Pro-cision Flo™][exclusive][applicator [tube][easily penetrates hair][fur][coat] for [improved][direct] application [directly to your cat's skin]
 Easy to apply [identify][use] applicator [tube]
 Cat head shape [applicator][tube] for cats [cat head = cats]
 The right choice [applicator][tube] for the right pet
 Make [Select] the right choice [applicator][tube][shape]
 Choice [selection] is simple
 Easy choice

Simple choice delivery system
 Easy to use applicator [tube] [provides direct on-animal protection]
 Longer Applicator [tube][tip] for easy application [to long-haired cats]
 Longer tube [applicator][tip] is ideal for long-haired [cats]
 Helps Prevent [misapplication on dogs] misuse on dogs with unique [specially designed] applicator [tube] design
 Cat head shape prevents misuse [misapplication][on dogs]
 Unique tube [applicator] design (cat shape) helps prevent misuse/misapplication [on dogs]
 EZ-squeeze [Easy squeeze] tube [applicator][shape]

(Product Claims)

- Odorless
- Clean fresh scent
- Effective Control [Relief][Prevention]
- Fast [Quick] acting [Relief]
- Starts working by contact
- Dual-action for immediate and long-lasting effects
- Quick acting, long lasting [treatment]
- Long lasting and easy to use [apply]
- [Flea prevention] Helps stop itching and scratching [from flea bites]

Thermoform claims

[disposable] [liquid dispensing] tube [cartridge][vial]
 [brand name][disposable][liquid dispensing] [tube][vial] tip [helps][to] spread out liquid [on your][cat/kitten]
 Unique [cartridge] [tube][vial] with flow control
 [no mess][application][tube][cartridge][vial]

Promotional Package Copy

One month [dose] free
 One free month supply [dose] included
 Bonus pack

(Brand claims)

[Brand] protecting pets for over 30 years
 We (Brand) put(s) your pet(s) first
 [Brand] putting (your pet) pets first
 Right choice = best defense
 Perfect choice
 [Brand] – caring & committed
 [Brand] makes the choice simple

(IGR claims)

From ZODIAC®, the originator of Insect Growth Regulator [IGR] technology
 [Plus][Contains][With] PRECOR® [vIGRen®], the first insect growth regulator for flea control
 Contains [Features] an Insect Growth Regulator (IGR) to inhibit the development of flea eggs
 Flea control for cats with [PRECOR®][vIGRen®] Insect Growth Regulator (IGR)
 [(S)-Methoprene] Insect Growth Regulator (IGR) interrupts the development of the flea life cycle at the egg stage
 [(S)-Methoprene] Insect Growth Regulator (IGR) prevents the development of flea eggs into adult fleas [inhibits the development of flea eggs into adult fleas]
 Controlling flea reproduction is the first step in controlling flea populations on your cat and in your home
 [(S)-Methoprene] Insect Growth Regulator (IGR) prevents flea reinfestation on your cat and in your home
 Flea treatment and preventative with an [insecticide] adulticide and Insect Growth Regulator (IGR)

(Formula claims)

Etofenprox provides a novel [smart] approach to flea, deer tick, and mosquito control

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Advanced Formula [for cats & kittens]
Features [Contains] an [insecticide] adulticide to kill [and/or][control] adult fleas [deer ticks, and mosquitoes]

(Prevention claims)

- Preventing fleas and deer ticks from infesting your cat is much easier than treating an existing problem;
- Flea prevention has never been easier
- An excellent preventative, offering protection against fleas
- Prevents flea, deer tick, and mosquito infestations
- Prevents flea recurrence
- Control flea infestations by preventing them
- Flea prevention is the best flea control strategy
- Quick and sure flea, deer tick, and mosquito prevention
- A quick and sure way to avert a flea problem is to [prevent it] use a preventative
- It is far easier to prevent fleas than to control them
- Flea control involves [requires] preventative measures [for your cat/kitten (12 weeks of age and older)]
- [[Year-round][Flea Treatment][Preventative]
- Use a flea preventative year-round (to prevent painful bites, itching and scratching, discomfort)

(FRONT PANEL)

ACTIVE INGREDIENTS:

(S)-Methoprene (CAS # 65733-16-6) 3.6%
 Etofenprox (CAS # 80844-07-1) 40.0%

OTHER INGREDIENTS: 56.4%

Total 100.0%

KEEP OUT OF REACH OF CHILDREN

See back panel for additional Precautionary Statements

EPA Reg. No. 2724-504
EPA Est. No.

Net Contents:
Lot Number:

[Specially formulated for cats [& kittens (12 weeks of age and older)]]][For use on cats [& kittens (over 12 weeks of age)]][Do not use on other animals]

INTRODUCTION:

[RF2004CCSO is a topically applied [long-lasting] product specifically formulated for cats and kittens with [containing] [it also contains] an insect growth regulator (IGR)[S-Methoprene][to prevent and control flea infestations][to kill fleas before they hatch][which prevents flea eggs from maturing into biting adults]. It [This product] also contains the highly effective flea, deer tick, and mosquito killing agent [Etofenprox][Brand Name], which kills biting adult fleas, deer ticks, and mosquitoes your cat may acquire from its surroundings. A single application of RF2004 (CCSO) will provide egg hatch inhibition for up to 30 days [1 month][4 weeks]. Each package contains enough product for xx monthly applications (xx days of protection [control]). RF2004 (CCSO) provides relief from flea infestations for up to 1 month [4 weeks] by killing adult fleas on your cat or kitten and flea eggs in your home. Adult fleas can live on your cat while producing vast numbers of eggs, which drop off your cat and develop in the surrounding environment. Normal insecticides will not kill the flea eggs, but RF2004 (CCSO) [is designed to] kill(s) adult fleas and flea eggs, breaking the flea life cycle and providing your cat relief from flea bites at the same time.

After application, your cat's [ordinary][innate][native] skin oils [disperse] carry RF2004 (CCSO) over your cat's body for protection against biting adult fleas and the development of flea eggs. [(product) may stain leather and suede fabrics for (24)(24 to 48) hours after application.] Once adult fleas are evident on your

cat, there is likely an infestation of flea eggs and flea larvae in your home. To completely kill the existing flea population, you may need to treat your home and your cat's bedding (home sprays, foggers), as well as your yard (yard spray/outdoor fogger) with traditional flea products approved for use on cats, around the home, or in your yard. RF2004 (CCSO) can be used in conjunction with other ZODIAC [HARTZ®] premise products. As with all flea products, they are [RF2004 (CCSO) is] most effective when used as part of a total program aimed at reducing all stages of fleas in the cat's environment. ZODIAC [HARTZ] products [They] are designed to complement each other in an integrated program for flea, deer tick, and mosquito management. To assure proper treatment, we recommend use of ZODIAC [HARTZ] products as directed to treat all pets in the household, as well as the indoor and outdoor home environments.]

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

IMPORTANT! READ ENTIRE LABEL BEFORE EACH USE. FOR USE ONLY ON CATS OR KITTENS (12 WEEKS OF AGE OR OLDER). DO NOT USE ON CATS OR KITTENS LESS THAN 3 POUNDS or 12 WEEKS OF AGE. DO NOT USE ON OTHER ANIMALS!

USE RESTRICTIONS

- For indoor use only.
- Apply this product once every 30 days. Do not retreat more than once per month.
- Do not apply this product to cats or kittens less than 3 pounds and/or less than 12 weeks of age.
- [(For the 3 lb. to < 5 lb. product) Do not apply to cats/kittens weighing less than 3 lbs.]
- [Do not apply to cats weighing less than 5 lbs.]
- Do not get this product in your cat's/kitten's eyes.
- Do not allow your cat/kitten to ingest this product.
- Do not use more than one applicator per cat/kitten and do not apply more than once per month.

[This product contains xx monthly dosages [one monthly dose], each [0.034 fl oz and 0.061 fl oz (1 and 1.8 ml [cc])].

[1 ml [cc] [0.034 fl oz] dose for use ONLY on cats/kittens (12 weeks of age and older) over 3 lbs but less than 5 lbs.

1.8 ml [cc] [0.061 fl oz] dose for use ONLY on cats and kittens (12 weeks of age and older) and 5 lbs. and over (Same size applicators with different fill amounts)]

[APPLICATION METHOD]

[Bend at perforation and tear off 1st month's applicator.] Hold [applicator] upright [and bend area of plastic at perforation, tear off and discard.] [Hold applicator upright] and snap tip back, away from face and body.

Prior to application of the product, gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the tip of the [applicator] tube on the cat's exposed skin and squeeze out the [entire] contents of the [applicator] tube onto the cat's skin. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried. Repeat application once monthly.

ALTERNATE PACKAGING DIRECTIONS 1 (CAT-HEAD APPLICATOR)

[Bend at perforation and tear off 1st month's applicator.] Hold [applicator] upright and bend numbered area of plastic at perforation, tear off and discard. Hold applicator upright away from face and body and use scissors to cut secure seal applicator tip. Prior to application of the product, gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the tip of the [applicator] tube on the cat's exposed skin and squeeze out the [entire] contents of the [applicator] tube onto the cat's skin. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried. Repeat application once monthly.

ALTERNATE PACKAGING DIRECTIONS 2

Remove one applicator tube from the package and hold in an upright position (pointed away from your face). Hold bottom of tube with one hand. With other hand, snap cap off. Prior to application of the product, gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the tip of the [applicator] tube on the cat's exposed skin and squeeze out the [entire] contents of the

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[applicator] tube onto the cat's skin. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried. Repeat application once monthly.

ALTERNATE PACKAGING DIRECTIONS 3 (for new subregistrant ampoule openings)

1. Remove one applicator [tube] from the package and hold in an upright position pointed away from your face.
2. Twist dispensing tip clockwise about ½ turn while pushing down to break the applicator's [tube's] seal. Do not remove the dispensing tip.
3. Prior to application of the product, using the dispensing tip of the applicator [tube], gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the dispensing tip of the applicator [tube] on the cat's exposed skin and squeeze out the [entire] contents of the [applicator] tube onto the cat's skin. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried.
4. Repeat application once monthly.

ALTERNATE PACKAGING DIRECTIONS 4 (for new subregistrant ampoule openings)

1. Remove one applicator [tube] from the package and hold in an upright position pointed away from your face.
2. Twist dispensing tip clockwise about ½ turn until you feel it click into place. Do not remove the dispensing tip.
3. Prior to application of the product, using the dispensing tip of the applicator [tube], gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the dispensing tip of the applicator [tube] on the cat's exposed skin and squeeze out the [entire] contents of the [applicator] tube onto the cat's skin. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried.
4. Repeat application once monthly.

ALTERNATE PACKAGING DIRECTIONS 5 (for new subregistrant ampoule openings)

1. Remove one applicator [tube] from the package and hold in an upright position pointed away from your face.
2. Squeeze the middle of the dispensing tip at the grooved pad to break the inner seal. Do not remove the dispensing tip.
3. Prior to application of the product, using the dispensing tip of the applicator [tube], gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the dispensing tip of the applicator [tube] on the cat's exposed skin and squeeze out the [entire] contents of the [applicator] tube onto the cat's skin. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried.
4. Repeat application once monthly.

ALTERNATE PACKAGING DIRECTIONS 6

1. Remove one applicator tube from the package and hold in an upright position pointed away from your face.
2. Pull off cap. Turn the cap around and place on top of tube.
3. Simply press cap down to break the seal of tube. Remove cap carefully.
4. Prior to application of the product, gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the tip of the tube on the cat's exposed skin and squeeze out the entire contents of the tube onto the cat's skin. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried.
5. Repeat application [once every month][once monthly].

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STORAGE AND DISPOSAL: Pesticide Storage: Store in a cool, dry (preferably locked) area that is away from children and animals. Do not store unused applicators [tubes] separately from their packaging.

Container Disposal: If empty: Do not reuse empty applicator [tube]. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS: Repeated exposure to etofenprox can cause skin irritation.

HAZARDS TO ANIMALS: For External Use on Cats Only. **Do not use on kittens less than 12 weeks old.**

Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your cat/kitten with mild soap and rinse with large amounts of water. If signs continue, [please call 1-800-phone number or] consult a veterinarian immediately. Due to the bitter taste of the product, oral exposure could result in salivation. Be careful not to get any product in the cat's mouth during application. For multiple cat households, prevent the cats from grooming each other until the product has dried. If the salivation continues or other clinical signs are noted, please call 1-800-number.

Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

In case of an emergency or for product use information, call [phone number] or visit our Web site: [URL]

SIDE EFFECTS: Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or [Brand at 1-800-number]

Wellmark International
1501 East Woodfield Road 200W
Schaumburg, IL 60173
Made in USA

PRECOR® Insect Growth Regulator, vIGRen® Insect Growth Regulator, and ZODIAC® are registered trademarks of Wellmark International.

Adding a Dose Reminder section to appear as follows on the back panel:

First Monthly Application: Month _____ Day _____ Year _____
Second Monthly Application: Month _____ Day _____ Year _____
Third Monthly Application: Month _____ Day _____ Year _____
[Fourth Monthly Application: Month _____ Day _____ Year _____]

Optional marketing text for subregistrant

[TREATMENT SCHEDULE

Dosage: 1 applicator every 30 days per cat

Cat's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

12/
12

NOTES: _____

REMINDER: I purchased [Brand Name] _____ from _____]

To learn more about treating current infestations and preventing future outbreaks, please, visit our website: [URL]

[For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents) you may call 1-xxx-xxx-xxx, twenty four (24) hours per day, seven (7) days per week.

To learn more, visit [URL]

TEXT FOR LIQUID TUBE/CARTRIDGE/MIAL/Applicator:

Product Name

Etofenprox 40%, S-Methoprene 3.6%

KEEP OUT OF REACH OF CHILDREN

Use ONLY on cats/[kittens] (12 wks of age and older &) [weighing](5 lbs & over) (over 3 lbs but less than 5 lbs)

[READ ENTIRE LABEL BEFORE EACH USE] (OPTIONAL if space permits)

EPA Reg No. 2724-504

Net Contents

Lot Number:

[US Patent No. _____]